



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,581	11/09/2000	Ronald S. Vladyka JR.	FMC-1006US	2095

21302 7590 07/15/2003

KNOBLE & YOSHIDA
EIGHT PENN CENTER
SUITE 1350, 1628 JOHN F KENNEDY BLVD
PHILADELPHIA, PA 19103

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 07/15/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,581

Applicant(s)

VLADYKA ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Finality Withdrawn

1. The finality of the rejection of the Office action mailed October 30, 2002 is withdrawn for the reasons disclosed below.
2. The amendment filed April 30, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) The specification has been amended.
3. Claims 1-26 are pending in the case.
4. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (b) recites "drying the granulated microcrystalline cellulose at a controlled rate for a time sufficient to remove at least substantially all of the polar organic solvent from the granulated microcrystalline cellulose." Page 6, 1st paragraph of the instant specification defines the rate of controlled drying as carrying out the drying step with no more than a minimal input of heat or reduction in pressure for drying. This definition is insufficient and renders the claims vague and indefinite because the phrase "minimal input of heat" is a relative term, which renders the phrase "drying ... at a controlled rate" in Claim 1 indefinite. The phrases "minimal input of heat" and "drying at a controlled rate" are not defined by the claim, the specification does not provide a standard for

Art Unit: 1623

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Applicant's arguments with respect to Claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 2, and 4-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Asgharnejad et al (US Patent No. 6,123,964, already of record).

Applicants claim a method for preparing microcrystalline cellulose granules comprising the following steps:

- (a) granulating microcrystalline cellulose with a granulating fluid comprising water and a water-miscible, volatile, polar organic solvent to provide a granulated microcrystalline cellulose;
- (b) drying the granulated microcrystalline cellulose at a controlled rate for a time sufficient to remove at least substantially all of the polar organic solvent from the granulated microcrystalline cellulose without removing at least a substantial portion of the water from the granulated microcrystalline cellulose, and without extruding or spheronizing the granulated microcrystalline cellulose from granulation step (a); and
- (c) subsequent to step (b), removing at least a substantial portion of the water from the granulated microcrystalline cellulose.

Additional limitations in the dependent claims include: specific polar organic solvents; specific volume ratio of water to polar organic solvent in the granulating fluid ranging

Art Unit: 1623

from 85:15 to 15:85; specific ratio of granulating fluid to microcrystalline cellulose; adding to the granulating microcrystalline cellulose about 1% to about 30% by weight of a hydrocolloid prior to the drying step; coating the hydrocolloid onto the surface of the microcrystalline cellulose granules; and specific hydrocolloids.

The Asgharnejad et al patent discloses a process comprising the steps of (1) forming a powder blend of the active ingredient with a binder/diluent, a first diluent, a second diluent, and a disintegrant, using a mixer; (2) wet granulating the powder blend by adding a solution of ethanol/water to the powder blend; (3) drying the granules to remove the ethanol/water with heated air in a fluid bed dryer or tray dryer (see column 2, line 63 to column 3, line 6). See column 3, lines 21-29 of the Asgharnejad et al patent wherein the binder/diluent is pregelatinized starch; the first diluent is microcrystalline cellulose; and wherein it is indicated that the solution of ethanol/water is in a range of 0% to 80% ethanol in water (w/w). The ethanol/water solution used in the Asgharnejad et al patent meets the polar organic solvent requirement disclosed in the claims and the pregelatinized starch that is disclosed in the Asgharnejad et al patent embraces the presence of the hydrocolloid in the instantly claimed process. It is noted that the combination of ethanol, isopropanol, or t-butyl alcohol with water forms an azeotrope. For example, the percent composition of ethanol and water as an azeotrope is 95.6 % for ethanol and 4.4 % for water (see CRC Handbook of Chemistry and Physics, 60 edition, 1979-1980, page D-21, Compound No. 411). The minimum amount of water used as a granulating fluid in combination with the polar organic solvent set forth in the instant claims is 15 parts water as described in the water to polar organic solvent ratio of 15:85. The percent composition of the ethanol and water as an azeotropic liquid in the CRC Handbook shows that the instant claims set forth an excess amount of water. By having an excess amount of water, steps (b) and (c) of the instant claims only set forth a normal drying procedure for removing azeotropic liquids containing ethanol and water wherein there is an excess amount of water. Once all the azeotropic liquid (ethanol/water combination) is removed, the excess amount of water in the process still remains in the drying vessel, which applicants removes in step (c), probably at a different temperature or pressure than what was used in step (b). The

Art Unit: 1623

Asgharnejad et al patent also contains an excess amount of water along with the ethanol and water azeotrope combination, which would remain in the drying vessel after the initial removal of the ethanol/water azeotrope. See column 3, line 28 of the Asgharnejad et al patent wherein the combination of ethanol and water may preferably comprise as low as 5% ethanol, which is well within the range of having an excess amount of water with an azeotrope of ethanol and water. The excess water set forth in the granulating fluid of the instant claims causes the extra process step (step c) in the instant claims which would be an inherent feature of the process set forth in the Asgharnejad et al patent since the Asgharnejad et al patent also discloses excess water in the granulating fluid thereof. Accordingly, the above described method of the Asgharnejad et al patent anticipates the instantly claimed method for preparing microcrystalline cellulose granules.

10. Applicant's arguments with respect to Claims 1, 2, and 4-11 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

11. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964, already of record).

Applicants claim a method for preparing microcrystalline cellulose granules comprising the following steps:

- (a) granulating microcrystalline cellulose with a granulating fluid comprising water and a water-miscible, volatile, polar organic solvent to provide a granulated microcrystalline cellulose;
- (b) drying the granulated microcrystalline cellulose at a controlled rate for a time sufficient to remove at least substantially all of the polar organic solvent from the granulated microcrystalline cellulose without removing at least a substantial portion of the water from the granulated microcrystalline cellulose, and without extruding or spheronizing the granulated microcrystalline cellulose from granulation step (a); and
- (c) subsequent to step (b), removing at least a substantial portion of the water from the granulated microcrystalline cellulose.

Art Unit: 1623

Additional limitations in the dependent claims include: specific polar organic solvents; specific volume ratio of water to polar organic solvent in the granulating fluid ranging from 85:15 to 15:85; specific ratio of granulating fluid to microcrystalline cellulose; adding to the granulating microcrystalline cellulose about 1% to about 30% by weight of a hydrocolloid prior to the drying step; coating the hydrocolloid onto the surface of the microcrystalline cellulose granules; and specific hydrocolloids.

The Asgharnejad et al patent discloses a process comprising the steps of (1) forming a powder blend of the active ingredient with a binder/diluent, a first diluent, a second diluent, and a disintegrant, using a mixer; (2) wet granulating the powder blend by adding a solution of ethanol/water to the powder blend; (3) drying the granules to remove the ethanol/water with heated air in a fluid bed dryer or tray dryer (see column 2, line 63 to column 3, line 6). See column 3, lines 21-29 of the Asgharnejad et al patent wherein the binder/diluent is pregelatinized starch; the first diluent is microcrystalline cellulose; and wherein it is indicated that the solution of ethanol/water is in a range of 0% to 80% ethanol in water (w/w). The ethanol/water solution used in the Asgharnejad et al patent meets the polar organic solvent requirement disclosed in the claims and the pregelatinized starch that is disclosed in the Asgharnejad et al patent embraces the presence of the hydrocolloid in the instantly claimed process. It is noted that instant Claim 9 recites that the hydrocolloid is added to the microcrystalline cellulose granules after substantially all of the polar organic solvent has been removed from the granulated microcrystalline cellulose. However, no patentable difference in the final product from the product of the prior art is noted by adding the hydrocolloid after removal of the polar organic solvent. It is also noted that the combination of ethanol, isopropanol, or t-butyl alcohol with water forms an azeotrope. For example, the percent composition of ethanol and water as an azeotrope is 95.6 % for ethanol and 4.4 % for water (see CRC Handbook of Chemistry and Physics, 60 edition, 1979-1980, page D-21, Compound No. 411). The minimum amount of water used as a granulating fluid in combination with the polar organic solvent set forth in the instant claims is 15 parts water as described in the water to polar organic solvent ratio of 15:85. The percent composition of the ethanol and water as an azeotropic liquid in the CRC Handbook

Art Unit: 1623

shows that the instant claims set forth an excess amount of water. By having an excess amount of water, steps (b) and (c) of the instant claims only set forth a normal drying procedure for removing azeotropic liquids containing ethanol and water wherein there is an excess amount of water. Once all the azeotropic liquid (ethanol/water combination) is removed, the excess amount of water in the process still remains in the drying vessel, which applicants removes in step (c). The Asgharnejad et al patent also contains an excess amount of water along with the ethanol and water azeotrope, which would remain in the drying vessel after the initial removal of the ethanol/water azeotrope. See column 3, line 28 of the Asgharnejad et al patent wherein the combination of ethanol and water may preferably comprise as low as 5% ethanol, which is well within the range of having an excess amount of water with an azeotrope of ethanol and water. The method of the instant claims differ from the process of the Asgharnejad et al patent since the Asgharnejad et al patent further discloses the present of an active ingredient as part the process medium and include steps that lead to the preparation of a tablet which is not set forth in the instantly claimed method. However, the active ingredient and additional process steps does not negate the preparation of microcrystalline cellulose granules in the Asgharnejad et al patent. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention having the Asgharnejad et al patent before him to replace the ethanol and water solution having an active ingredient of the Asgharnejad et al patent with only an ethanol and water solution in view of their closely related structures and the resulting expectation of similar granulating properties. One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because the skilled artisan would have expected the analogous starting materials to react similarly.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964, already of record) as applied to Claims 1-13 above, and further in view of Flanner et al (US Patent No. 6,384,020, newly cited).

Applicants claim a method for preparing microcrystalline cellulose granules comprising the following steps:

- (a) granulating microcrystalline cellulose with a granulating fluid comprising water and a water-miscible, volatile, polar organic solvent to provide a granulated microcrystalline cellulose;
- (b) drying the granulated microcrystalline cellulose at a controlled rate for a time sufficient to remove at least substantially all of the polar organic solvent from the granulated microcrystalline cellulose without removing at least a substantial portion of the water from the granulated microcrystalline cellulose, and without extruding or spheronizing the granulated microcrystalline cellulose from granulation step (a); and
- (c) subsequent to step (b), removing at least a substantial portion of the water from the granulated microcrystalline cellulose.

Additional limitations in the dependent claims include: specific polar organic solvents; specific volume ratio of water to polar organic solvent in the granulating fluid ranging from 85:15 to 15:85; specific ratio of granulating fluid to microcrystalline cellulose; adding to the granulating microcrystalline cellulose about 1% to about 30% by weight of a hydrocolloid prior to the drying step; coating the hydrocolloid onto the surface of the microcrystalline cellulose granules; specific hydrocolloids;

The information set forth in the Asgharnejad et al patent in the above rejection of the claims under 35 U.S.C. 103 is incorporated into the instant rejection. Instant Claim 3 differs from the Asgharnejad et al patent by claiming isopropanol as the polar organic solvent, which is not disclosed in the Asgharnejad et al patent. However, the Flanner et al patent shows that the use of isopropyl alcohol (or isopropanol) as a granulating fluid in processes for the preparation of tablets is well known in the art (see column 5, line 65 of the Flanner et al patent).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the ethanol used as the granulating fluid in the process of the Asgharnejad et al patent with isopropyl alcohol in view of the recognition in the art, as evidenced by the Flanner et al patent, that use of isopropyl

Art Unit: 1623

alcohol as a granulating fluid are effective for preparing free flowing granules that are used in the preparation of tablets.

One of ordinary skill in this art would be motivated to combine the teachings of the Asgharnedjad et al patent with the teachings of the Flanner et al patent since both patents set forth processes for the preparation of tablets that prepare granules using a wet granulation formulation

13. Applicant's arguments with respect to Claim 3 have been considered but are moot in view of the new ground(s) of rejection.

14. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964, already of record) as applied to Claims 1-13 above, and further in view of Erkoboni et al (US Patent No. 5,725,886, already of record).

Applicants claim a method for preparing microcrystalline cellulose granules comprising the following steps:

- (a) granulating microcrystalline cellulose with a granulating fluid comprising water and a water-miscible, volatile, polar organic solvent to provide a granulated microcrystalline cellulose;
- (b) drying the granulated microcrystalline cellulose at a controlled rate for a time sufficient to remove at least substantially all of the polar organic solvent from the granulated microcrystalline cellulose without removing at least a substantial portion of the water from the granulated microcrystalline cellulose, and without extruding or spheronizing the granulated microcrystalline cellulose from granulation step (a); and
- (c) subsequent to step (b), removing at least a substantial portion of the water from the granulated microcrystalline cellulose.

Additional limitations in the dependent claims include: specific polar organic solvents; specific volume ratio of water to polar organic solvent in the granulating fluid ranging from 85:15 to 15:85; specific ratio of granulating fluid to microcrystalline cellulose; adding to the granulating microcrystalline cellulose about 1% to about 30% by weight of

a hydrocolloid prior to the drying step; coating the hydrocolloid onto the surface of the microcrystalline cellulose granules; specific hydrocolloids;

The information set forth in the Asgharnejad et al patent in the above rejection of the claims under 35 U.S.C. 103 is incorporated into the instant rejection. Instant Claims 12 and 13 differ from the Asgharnejad et al patent by disclosing hydrocolloids that are not recited in the Asgharnejad et al patent.

The Erkoboni et al patent shows that the hydrocolloids that are disclosed in instant Claims 12 and 13 are well known in the art. The Erkoboni et al patent discloses microcrystalline cellulose-hydrocolloid compositions and set forth examples of hydrocolloids in the paragraph bridging column 2 and column 3 of the patent that embraces the listed hydrocolloids in instant Claims 12 and 13. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the starch compound used in the process of the Asgharnejad et al with a hydrocolloid in view of the recognition in the art, as evidenced by the Erkoboni et al patent, that use of hydrocolloids in the preparation of a microcrystalline cellulose product are effective for forming an aqueous solution or dispersion.

15. Applicant's arguments with respect to Claims 12 and 13 have been considered but are moot in view of the new ground(s) of rejection.

16. Claims 14-16 and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US Patent No. 6,149,943, already of record).

Applicants claim a porous, granulated microcrystalline cellulose having a loose bulk density of from about 0.2 g/cc to about 0.4 g/cc and a mean particle size of from about 250 microns to about 1500 microns. Additional limitations in the dependent claims include the microcrystalline cellulose granules comprising 1% to about 30% by weight of a hydrocolloid; specific type of hydrocolloids; and the granulated microcrystalline cellulose composition in form of a tablet.

The McTeigue et al patent discloses microcrystalline cellulose particles having a particle size up to about 220 microns with a particle size standard deviation of from about 75 to about 200 microns (see column 1, line 54) and bulk density at about 0.40

grams/cubic centimeters (see column 2, lines 51 and 52), which embraces the microcrystalline cellulose granules of the instant claims. The McTeigue et al patent also discloses coating compositions, which may include the polymer systems disclosed in the Table at lines 40-67 of column 4. The polymer systems disclosed by McTeigue et al include coatings that are analogous to some of the hydrocolloids set forth in instant Claims 21-23. McTeigue et al further discloses preparations that involve combining coated particles with excipients, which are compressed to form tablets (see column 6, 2nd paragraph). Also see Examples 1 and 2 of the McTeigue et al patent whereby the examples disclose compositions comprising analogous microcrystalline cellulose granules, hydrocolloid, excipient and active ingredients that embraces the instantly claimed invention. Applicants amended the claims to indicate that the mean particle size of the microcrystalline cellulose is at least 250 microns. Although, the McTeigue et al patent only discloses the microcrystalline cellulose thereof as having a mean particle size up to about 220 microns, the particle size standard deviation of 200 microns that is disclosed in the McTeigue patent does suggest microcrystalline cellulose particles that have a particle size of at least 250 microns are present in the McTeigue et al patent. It is within the skill of an artisan to screen a desired microcrystalline cellulose particle size. Furthermore, regarding the differences in particle size of the microcrystalline cellulose, there is a distinction between a new article of commerce and a new article, which is patentable. Any change in form may render an article new in commerce. But to be patentable it must be more efficacious or possess new properties by a combination with other ingredients and not merely a change of form, which has the advantages which one skilled in the art would expect from the change. *Glue Co. v. Upton* (USSC 1878) 97 US 3, 24 L Ed. 985. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicant(s) invention to use the microcrystalline cellulose particles of the McTeigue et al patent that have a particle size of 250 microns, in view of their closely related structures and the resulting expectation of similar drug coating properties.

17. Applicant's arguments with respect to claims 14-16 and 18-26 have been considered but are moot in view of the new ground(s) of rejection.

18. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US Patent No. 6,149,943, already of record) as applied to Claims 14-16 and 18-26 above, and further in view of Kumar (US Patent No. 6,117,451, already of record).

Applicants claim microcrystalline cellulose granules having a loose bulk density of from about 0.25 g/cc to about 0.35 g/cc.

The information disclose in the above rejection against the McTeigue et al patent is applied in the instant rejection. The instant claims differ from the McTeigue et al patent by disclosing in Claim 17 that the microcrystalline cellulose granules have a loose bulk density of from about 0.25 g/cc to about 0.35 g/cc. The Kumar patent shows that the claimed density for microcrystalline cellulose is well known in the art by disclosing a density range of 0.20 to 0.45 g/ml for the microcrystalline cellulose thereof (see column 5, lines 46-48). Accordingly, it would have been obvious to one having ordinary skill in the art to substitute the microcrystalline cellulose having a density of 0.4 g/cc of the McTeigue et al patent for the microcrystalline cellulose that comprises a density range of 0.20 to 0.45 g/ml of the Kumar patent in view of the recognition in the art, as evidenced by the Kumar patent, that microcrystalline cellulose has inherent binding and superior tableting flow properties.

Arguments

19. Applicant's arguments filed August 5, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection of the claims over the McTeigue et al and Kumar patents on the grounds that the patents do not teach the granules, as claimed. However, this argument is not persuasive since there is no process step in the patents that involve spheronizing the microcrystalline cellulose. Also see column 2, lines 54-57 and Fig. 1 of the McTeigue et al patent whereby an irregular shape surface of the microcrystalline cellulose is indicated, which embraces microcrystalline cellulose in granular form.

Art Unit: 1623

Summary

20. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

21. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

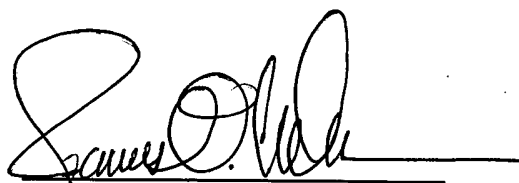
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600